Guidance on the Definition of Pharmacist Supervision as applied to Final Product Approval (Release) under Section 10 Aseptic Preparation Activities

The governance arrangements that need to be in place to enable Accredited Pharmacy Technician Final Product Approvers to carry out final product approval within an aseptic service operating under Section 10 exemption.

3rd Edition

September 2019

Endorsed and supported by:

Specialist Pharmacy Service

ACKNOWLEDGEMENT

Working group members

Mark Santillo (Chair)
Regional Quality Assurance Officer, South West

Linda Hardy
Regional Quality Assurance Specialist Pharmacist, Yorkshire

Scott Hillery
Production Manager, Kettering General Hospital

Erica Lieberman
Accountable Pharmacist Cytotoxic Chemotherapy Production Unit, City Hospital, Nottingham

Oonagh McGrath
Pharmacy Manager, Parenteral Services Unit, Bristol Haematology and Oncology Centre

Catherine Talbot
Project Manager and Education and Training Lead, St Mary's Pharmaceutical Unit (SMPU)

Ellen Williams
Education & Training Specialist Pharmacy Technician, South West Medicines Information & Training

With thanks to Tim Root, Specialist Pharmacist, NHS Specialist Pharmacy Service for providing the introduction

Comments should be submitted to:
Mark Santillo mark.santillo@nhs.net

Document History	Issue date and reason for change
Edition 1	Issued July 2014
Edition 2	Issued January 2018 Total rewrite of the introduction. Updates in line with QAAPS 5th Edition. Change to point 11 – Pharmacists now strongly recommended to undertake a course (this was marked as essential in the original version but this is not enforceable).
Edition 3	Re-ordered and updated to improve clarity. Clarification of title and addition of sub-title. Reduced requirement for Authorised Pharmacist to approve individual worksheets for accredited pharmacy technician final product approval where validated electronic systems or fixed worksheets are used. Inclusion of a flow diagram to help decision making.
Edition 4	

PURPOSE OF THIS DOCUMENT

The aim of this document is to help guide Chief Pharmacists to ensure that the legal requirements for *direct supervision by a pharmacist* of aseptic dispensing activities carried out under Section 10 exemption, are consistently and reliably met in their organisation.

Scope

1. In order to achieve an acceptable level of supervision it is necessary to describe the requirements at three levels.
    - Organisational Level
    - Day to Day Operational Level
    - Individual Product Level

2. This guide covers all aseptic dispensing activities *except* dispensing of Investigational Medicinal Products which are covered by Paragraph 37 of the Clinical Trials Regulations and cannot be carried out under Section10 exemption[1].

3. With suitable additional training this guideline can be extended to cover final product approval of doses of *licensed medicines* for use in clinical trials.

4. This guidance document applies to section 10 aseptic services final product approval. Intrathecal products can be included as long as the final product approver is trained, competent and named on the intrathecal register for this task.

5. Subject to suitable training and understanding of the status and requirements, this guidance can also be applied to the release of doses of named-patient, ready-to-administer products bought from third party suppliers.

Summary

This document

1. Describes a framework under which Pharmacy technicians can be authorised as Accredited Final Product Approvers whilst the requirement for supervision of an Authorised Pharmacist is met.

2. Defines the roles of the Chief Pharmacist, the Accountable Pharmacist, the Authorised Pharmacist and the Accredited Product Approver (Section 10 Releasing Officer).

3. Defines product and process-related requirements, the Final Accuracy Check and the meaning of *Product Approval.*

Background

"A strong quality culture is built upon:

- ***knowledge** of what is important, and how a process achieves critical quality attributes*
- ***diligence**, by fostering awareness that everyone contributes to product quality, and understanding that "my actions impact the patient and the company"*
- ***vigilance** by individuals who know what 'right' and 'wrong' look like in their process, and a mechanism for management to be aware of problems*
- ***senior management commitment** to being visible and transparent in decision-making so that positive outcomes can be seen from the diligence and vigilance efforts. This is more than the organisation's mission statement – it's 'walking the talk'."*

  David Churchward, Expert GMDP Inspector, MHRA, February 2019

The NHS Aseptic Services Accreditation Working Group, working closely with the South West Product Approval Accreditation Programme developed and published the definition of Supervision as it can be applied to Section 10 Aseptic Preparation Activities in July 2014. The aim of the definition and associated programme was to allow for Pharmacy Technicians to act as final product approvers. Following incorporation of standards to allow for supervision defined within the document into the Quality Assurance of Aseptic Preparation Services 5th Edition[2], this was updated to version 2 in January 2018. However, implementation of the full requirement for supervision on a product by product basis, by an Authorised Pharmacist signing each worksheet, has proved onerous and would seem excessive particularly where fully validated electronic systems are in-use for worksheet generation.

The third version of this document has therefore been produced to allow more flexibility on this matter whilst continuing to show suitable supervision by Authorised and Accountable Pharmacists as required in law. The focus is on the robustness of the systems used for prescribing and worksheet generation and also the risk areas which may still exist.

This definition has been considered by the NHS Pharmaceutical Quality Assurance Committee and the Pharmaceutical Aseptic Services Group and agreed by both of these bodies.

The definition underpinned the South West Product Approval Programme which completed its pilot stages in 2013 and has formally been launched as an approved programme. A second programme is now run from the East Midlands. The NHS Aseptic Services Accreditation Working Group is focussed on supporting the wider roll out of this initiative.

It must be noted that the definition of supervision cannot be considered in isolation and must be fully supported by a framework that gives the same levels of resource, governance and oversight that has been incorporated into the existing programmes for final product approvers (Product Approval Accreditation Programme (PAAP)), in line with the national approved template.

Frameworks must be approved by the NHS Aseptic Accreditations Working Group in advance of implementation[4].

Definitions

Accountable Pharmacist - The pharmacist responsible for all aspects of the services within an aseptic preparation unit. The duties of the Accountable Pharmacist include the approval of all systems of work and documentation used in the unit. This person is also an Authorised Pharmacist.[2]

Authorised Pharmacist - The person designated in writing by the Accountable Pharmacist to supervise the aseptic process and release the product for use.[2]

Final Accuracy Check – Checking all details of the product and production process against the worksheet. Note this is carried out prior to final approval of the product.

Product Approval – Approval of the product as being suitable for issue to and administration to the patient. This must take place by an accredited product approver against all relevant documentation and the prescription and must include a visual and physical examination of the product. The Accredited Product Approver should also carry out all of the checks listed in 14.10 of QAAPS[2] before releasing the product.

Supervision – Supervision of the aseptic preparation of medicines in line with this policy must always be provided by an Authorised Pharmacist.

Framework for the definition of supervision as applied to Section 10 aseptic preparation activities

1. The concept of supervision as applied to The Medicines Act 1968 Section 10[i] aseptic preparation activities is complex and multi factorial. Therefore it is necessary to define how Pharmacy Technicians can be final product approvers whilst maintaining the supervision from an Authorised Pharmacist

2. An Accredited product approver is defined as An Authorised Pharmacist or a Pharmacy Technician who has been approved through a nationally recognised accreditation programme for product approval.

3. All staff involved in the process of final product approval have a professional responsibility for their own actions.

4. This framework seeks to describe the elements of the systems that organisations must ensure are in place at all times to provide an adequate level of supervision by an Authorised Pharmacist for Section 10 aseptic preparation activities when product approval is carried out by a Pharmacy Technician Final Product Approver.

5. In order to achieve an acceptable level of supervision it is necessary to describe the requirements in three levels. These may be defined as:

- Organisational Level requirements
- Day to Day Operational Level requirements
- Individual Product Level requirements

Organisational Level Requirements

Chief Pharmacist

6. The Chief Pharmacist is defined as "The pharmacist responsible for the pharmacy service within a corporate body." [2]

7. The Chief Pharmacist holds ultimate responsibility for the adequate resourcing of the aseptic preparation service to ensure that it meets the defined national standards.[2]

8. The Chief Pharmacist is also responsible for ensuring that a policy on Section 10 aseptic preparation is in place and that where this allows delegated product approval to Pharmacy Technicians, this has specific formal organisational Board level agreement.

Accountable Pharmacist

9. The Accountable Pharmacist together with the Chief Pharmacist must ensure that an effective and comprehensive Pharmaceutical Quality System is in place within the unit. This must be confirmed by EL (97)52[3] audit findings and meet the entry criteria for the National Accreditations Framework.

10. The Accountable Pharmacist must ensure that robust systems are in place to train, assess competence and authorise individuals to carry out the product approval process. For Pharmacy Technicians these systems must comply with the National Accreditation Framework requirements[4]. For Pharmacists new to the role this is also strongly recommended.

11. There must be an appropriate reporting structure so that all accredited product approvers are accountable directly to the Accountable Pharmacist for this activity and that this is reflected in their job description.

Chief Pharmacist and Accountable Pharmacist

12. The Chief Pharmacist and Accountable Pharmacist must agree a suitable management structure within the unit to ensure that the requirements of this framework are met at all times the unit is operational.

Day to Day Operational Level Requirements

Authorised Pharmacist

13. An Authorised Pharmacist must provide an acceptable level of supervision for the unit as defined within this document. They must approve the unit for the preparation of items on a daily basis and ensure that any open quality exceptions are communicated to accredited product approvers. This must occur before any items are released and must be documented.

14. If they cannot approve the unit for use then the issue must immediately be referred to the Accountable Pharmacist or deputy if the Accountable Pharmacist is absent.

15. An Authorised Pharmacist must be physically present within the unit for a sufficient period of the time during each session to discharge their professional responsibility.

16. There must be a formal review of the session's activities by the Authorised Pharmacist at the end of each session (i.e. the session for which they are the designated Authorised Pharmacist). The following may be considered as part of this review:

    - A review of a sample of worksheets of products released by accredited Pharmacy Technician product approvers during the session
    - A review of any deviations (Authorised Pharmacist release required for items where there has been a deviation)
    - A review of monitoring logs for the unit.

The Accountable Pharmacist must ensure that the Authorised Pharmacist does complete a session review at the end of each session.

Accredited Product Approver (Section 10 Releasing Officer)

17. The authorisation to use the unit should be signed each day by all accredited product approvers to show that they have acknowledged any ongoing or outstanding deviations within the unit and that available staffing and skill mix are appropriate for the anticipated level of preparation activity and that all scheduled monitoring and cleaning activities have been undertaken.

Individual Product Level requirements

Authorised Pharmacist

18. QAAPS 5th edition[2] states that the Authorised Pharmacist must carry out the Aseptic Services verification process for all items and ensure that a clinical check has been completed by a suitably qualified pharmacist. This section from QAAPS 5th edition[2] is reproduced below:

> **4.4 Aseptic services verification**
>
> 4.4.1 The Authorised Pharmacist should carry out the aseptic services verification process and as part of this ensure that a clinical verification has been completed in accordance with the specific organisational policy.
>
> 4.4.2 The aseptic services verification should include the following checks:
>
> - The prescription has been clinically verified
> - The prescribed constituents are compatible and the formulation is stable (see Chapter 6: Formulation, stability and shelf life)
> - The product is the correct presentation for the intended route of administration.
>
> 4.4.3 A record should be made on the worksheet indicating who carried out the verification of each prescription.

19. However, for some systems particularly where there are fully validated and controlled linked prescribing and worksheet systems in use, which have been approved by the Accountable Pharmacist, it will not be necessary for the Authorised Pharmacist to review and sign each worksheet as long as a robust process is described in Standard Operating Procedures (SOPs). The following sections set out the requirement in each situation.

A. Linked electronic prescribing and worksheet and label printing systems fully validated and approved by the Accountable Pharmacist, or a stand-alone fully validated electronic worksheet and label printing system approved by the Accountable Pharmacist but not fully linked to the electronic prescribing system or where low risk paper prescription templates are used.

i) The range of such products which are suitable for authorised Pharmacy Technician final product approval should be defined within an SOP, alternatively a suitable statement could be included on the relevant worksheet templates. For stand-alone worksheet and labelling systems the Accountable Pharmacist may want to exclude certain products from the list based on any risk of incorrect worksheet selection (i.e. more than one route, more than one concentration of starting material available, specific paediatric worksheets etc.)

ii) Worksheet preparation should not take place ahead of pharmacist clinical pharmacy verification of the prescription; alternatively there must be a process to ensure that pharmacist clinical screening has been carried out and documented ahead of product approval

iii) The Pharmacy Technician product approver must not have been involved in any part of the preparation of the product prior to product approval.

iv) **Any alterations to the worksheet must be considered as a deviation and must be referred to the Authorised Pharmacist for aseptic services verification.**

B. Fixed formulation worksheets

i) Where no tailoring or hand completion of calculations is required, the process should be clearly described in SOPs and the worksheet should be annotated appropriately as suitable for Accredited Pharmacy Technician final product approval.

ii) Any alterations to the worksheet must be considered as a deviation and must be referred to the Authorised Pharmacist for aseptic services verification.

C. Other systems (worksheets as paper templates completed by hand, electronic worksheets allowing flexibilities, where systems are still being validated or have yet to be approved by the Accountable Pharmacist.

i) The Authorised Pharmacist must approve each worksheet either as being suitable for delegated product approval or as requiring approval by an Authorised Pharmacist only. This process must be fully described in a specific SOP and in line with the requirements within this document.

ii) There may be some circumstances where in the event of certain planned deviations being in place, delegated product approval may still be possible. Any such decision must be as a result of formal, documented risk assessment of the planned deviation which has been approved by the Accountable Pharmacist.

20. The designated Authorised Pharmacist must be easily contactable and available for advice at any time during the working day.

21. The designated Authorised Pharmacist must be able to physically attend the unit immediately in the event of an urgent requirement.

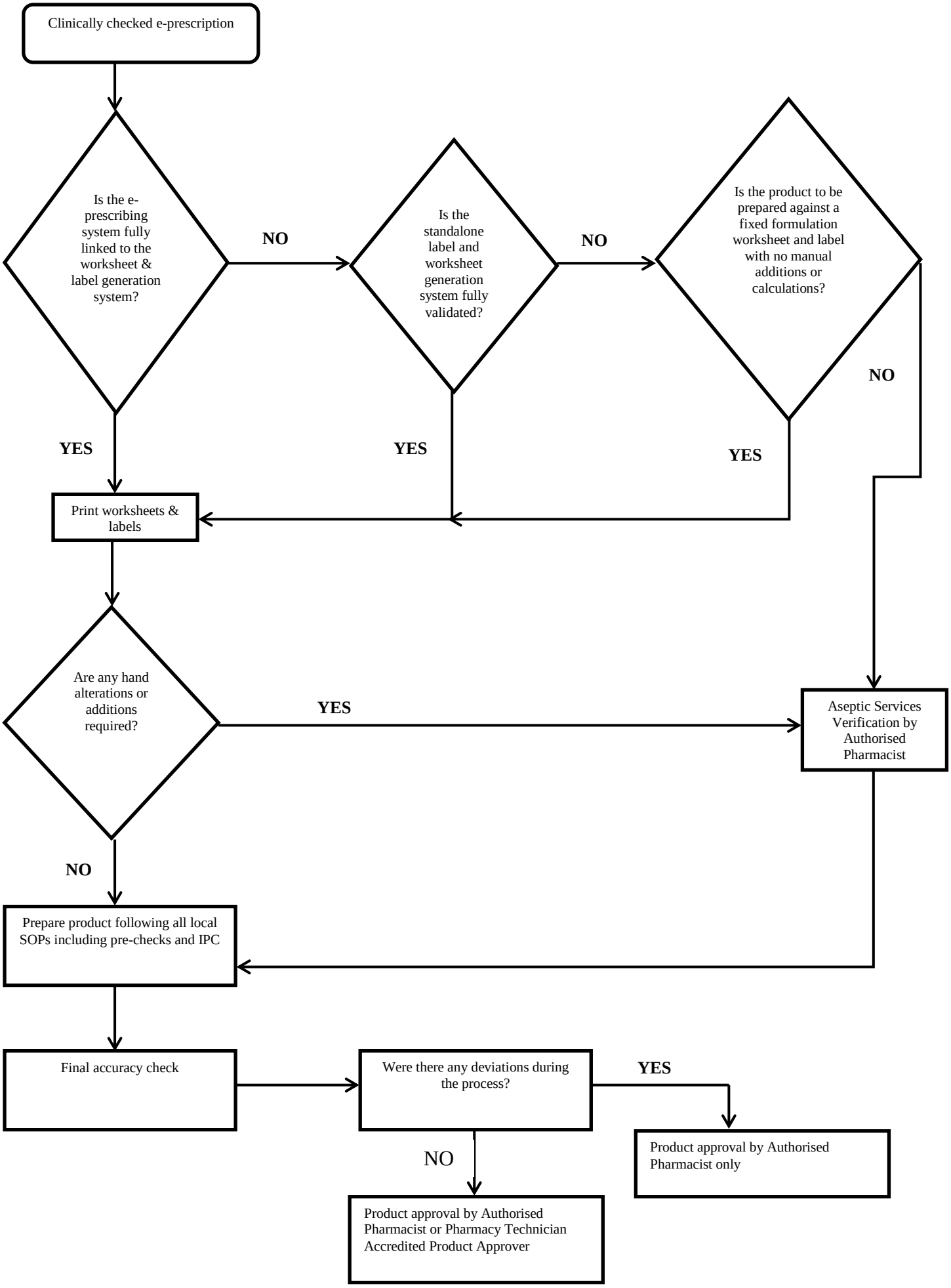
22. Any items where there has been an unplanned deviation or non-conformance during the preparation process, where the product may still be deemed suitable for use may only be released by the Authorised Pharmacist.

Accredited Product Approver

23. Pharmacy Technician accredited product approvers must meet all the requirements of the National Accreditation Framework[4] and hold appropriate certification.

24. The accredited product approver must only release those product types for which they have demonstrated competency and been authorised for.

25. The accredited product approver must be registered with, and therefore, follow that standards ethics and performance of, the General Pharmaceutical Council or Pharmaceutical Society of Northern Ireland (PSNI).


Clinically checked e-prescription
Is the e-prescribing system fully linked to the worksheet & label generation system?
NO
Is the standalone label and worksheet generation system fully validated?
NO
Is the product to be prepared against a fixed formulation worksheet and label with no manual additions or calculations?
NO
YES
YES
YES
Print worksheets & labels
Are any hand alterations or additions required?
YES
Aseptic Services Verification by Authorised Pharmacist
NO
Prepare product following all local SOPs including pre-checks and IPC
Final accuracy check
Were there any deviations during the process?
YES
Product approval by Authorised Pharmacist only
NO
Product approval by Authorised Pharmacist or Pharmacy Technician Accredited Product Approver

References

1. The Medicines Act, 1968 (as amended) Section 10

2. Quality Assurance of Aseptic Preparation Services, 5th Edition, A. Beaney, Royal Pharmaceutical Society, NHS Pharmaceutical Quality Assurance Committee ISBN 978-0-85711-307-8

3. Department of Health (1997) Executive Letter (97)52 Aseptic Dispensing in NHS Hospitals. London, NHS Executive

4. Nationally Recognised Competency Framework for Pharmacists and Pharmacy Technicians: Product Approval (Release) in Aseptic Services under Section 10 exemption (NHS Aseptic Services Accreditations Working Group, July 2014, update due for publication September 2019) http://www.swmit.nhs.uk/education-training/technical-pharmacy-services/product-approval.aspx

5. Standards of conduct, ethics and performance, General Pharmaceutical Council, May 2017.